REMARKS

The applicant has considered the Office Action of January 8, 2004 and offers the above amendments along with these remarks in response thereto. Withdrawal of all objections and rejections is respectfully requested.

Specification

The objections to the specification have been obviated with the amendments indicated above in accordance with the Examiner's suggestions. This includes the objection under 35 U.S.C. § 132. Withdrawal of all objections is requested.

Declaration

The applicants acknowledge the withdrawal of the objection to the Declaration.

35 U.S.C. § 112, First Paragraph

The Examiner has rejected certain amendments to claim 1 as not complying with the written description requirement. In particular, amendments to steps (b), (c) and (d) have been rejected despite the fact that the subject matter of the invention as originally disclosed is clearly understood and conveyed to one skilled in the art in accordance with the statute. Specifically, each of the introduced phrases are literally inherent in practicing the invention as originally disclosed and claimed. The Examiner has even admitted that the material "may be implicit or inherent to the disclosure" but does not have "clear antecedent basis." The standard for the written description is not, however, "clear antecedent basis" but rather whether one skilled in the art could "make and use" the invention as disclosed.

Specifically, the Examiner rejected the amendment to claim 1, step (b), which requires that the "diameter of the vessel into which a stent-graft will be placed" be determined. This limitation is so basic to any stent-graft deployment for aneurysm repair that one skilled in the art reading the present disclosure would clearly understand this to be a part of the invented method. Specifically, the description and drawings are replete with examples of the fact that the stent-graft of the present invention is placed into a vessel to bridge an aneurysm such that

the stent-graft diameter when deployed is at or slightly larger than the vessel diameter. See, for example, Figures 5-11 and related description. If no determination of the vessel diameter is made, multiple stent-grafts would have to be inserted and withdrawn by trial and error. This is simply not how these deployments are done, and one skilled in the art reading the present description of the invention would understand this limitation to be a part of the invention.

As to claim 1, step (c), the Examiner rejected the introduction of the language, "which maximum diameter [of the stent-graft] is greater than the vessel diameter of step (b) . . . ." as not having adequate support. It is completely impossible to deploy a stent-graft into a vessel to repair an aneurysm if the maximum possible diameter of the stent-graft is less than the vessel diameter. Not only would the stent-graft not stay in place, blood would flow outside of the graft and into the aneurysm. This is the very thing sought to be prevented in bridging the aneurysm with the stent-graft to begin with. This limitation on the maximum diameter of the stent-graft present in this step would clearly be known to one skilled in the art reading the disclosure of the present invention.

With regard to claim 1, step (d), which covers the trimming of the stent graft to a particular length prior to deployment, the Examiner has rejected the language describing the length to which the stent should be trimmed, namely to a "length that is greater than the length of the aneurysm when the stent-graft is dilated to its maximum diameter . . . ." As above, this aspect of the trimming step would be clearly known to one skilled in the art reading the invention disclosure. Indeed, if the stent-graft were trimmed to a length ***less*** than the length of the aneurysm when the stent-graft is dilated to its maximum diameter, the entire purpose of the invention would be lost. Moreover, if the stent-graft could shorten to a length *less* than the length of the aneurysm at full radial dilation, it would become dislodged. The very purpose of the invention as described throughout the specification and prosecution is to restrict the maximum diameter (radial dilation) to a point that ***prevents*** shortening of the stent beyond a catastrophic point and subsequent dislodgement. Therefore, this limitation on the trimming step is adequately disclosed in the specification.

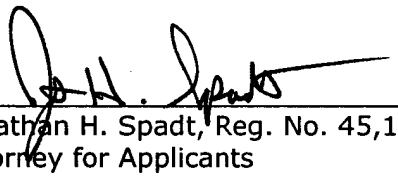
The applicants respectfully assert that a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The Examiner has the initial burden of presenting by a

preponderance of the evidence *why a person skilled in the art would not* recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. MPEP 2163.04. (emphasis added).

The applicants respectfully assert that the above burden has not been met. Other than noting that no "clear antecedent basis" exists in the specification, while simultaneously acknowledging that there is inherent disclosure, the Examiner has not presented any evidence, much less a preponderance of evidence, why a person skilled in the art would not recognize in the applicant's disclosure a description of the invention defined by the claims as pending. In addition to the lack of evidence, it is respectfully submitted that the arguments presented above establish that indeed one skilled in the art would recognize, in the present disclosure, the invention as claimed and be able to practice it fully and clearly.

If the Examiner thinks a declaration by one skilled in the art asserting the above arguments would be beneficial, one will be provided. Alternatively, it is respectfully requested that all rejections under 35 U.S.C. § 112, first paragraph be withdrawn. It is believed by the applicant and his representative that this case is in condition for allowance. Early and favorable notification to this effect along with a Notice of Allowance is respectfully requested.

Respectfully submitted,



Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

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☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2600

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